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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,936	05/31/2000	Michael G. Kahn M.D. Ph.D	FAST-01000US0-WSW	5001
22470 7590 02/23/2007 HAYNES BEFFEL & WOLFELD LLP P O BOX 366 HALF MOON BAY, CA 94019			EXAMINER NAJARIAN, LENA	
			ART UNIT	PAPER NUMBER
			3626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/584,936		KAHN M.D. PH.D ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Lena Najarian		3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7- 30, 36, 45-109, 118, 137, 139 and 140 is/are pending in the application.
- 4a) Of the above claim(s) 7, 12-30, 36, 45-109, 118 and 137 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-11, 139 and 140 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Notice to Applicant***

1. This communication is in response to the amendment filed 12/6/06. Claims 1-5, 8-11, and 139-140 have been examined. Claims 1, 4, 5, 8, 10, and 11 have been amended. Claims 6, 31-35, 37-44, 110-117, 119-136, and 138 have been canceled. Claims 7, 12-30, 36, 45-109, 118, and 137 have been withdrawn. Claim 140 is newly added.

### ***Claim Objections***

2. The objection to claims 8, 10, and 138 is hereby withdrawn due to the amendment filed 12/6/06.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 4, 5, 8-11, 139, and 140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Briegs et al. (US 7,054,823 B1).

(A) Referring to claim 1, Colon discloses at least one computer readable medium collectively carrying a machine readable database identifying (abstract of Colon):

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first patient eligibility criteria for a first clinical trial protocol (col. 6, lines 39-42 of Colon); and

a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow tasks to be performed for a particular patient (col. 6, line 39 – col. 7, line 10 of Colon).

Colon does not disclose wherein the post-enrollment workflow tasks include at least one element of the group consisting of a post-enrollment instruction to have a specified test performed on the patient, and a post-enrollment instruction to have a specified CRF completed for the patient.

Briegs discloses wherein the post-enrollment workflow tasks include a post-enrollment instruction to have a specified CRF completed for the patient (col. 48, lines 1-14 of Briegs).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Briegs within Colon. The motivation for doing so would have been to review the status of the subjects (col. 49, lines 29-36 of Briegs).

Insofar as the claim recites “at least one element of the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 2, Colon discloses wherein said database further identifies preliminary patient eligibility criteria applicable to said first clinical trial protocol (col. 2, lines 5-8 of Colon).

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(C) Referring to claim 4, Colon does not disclose wherein said first plurality of workflow tasks includes the post-enrollment instruction to have a specified CRF completed for the patient.

Briegs discloses wherein said first plurality of workflow tasks includes the post-enrollment instruction to have a specified CRF completed for the patient (col. 48, lines 1-14 of Briegs).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Briegs within Colon. The motivation for doing so would have been to review the status of the subjects (col. 49, lines 29-36 of Briegs).

(D) Referring to claims 5 and 140, Colon does not disclose wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient.

Briegs discloses wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient (col. 3, lines 43-48 of Briegs).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Briegs within Colon. The motivation for doing so would have been to indicate the different course of action to be taken for the patient (col. 3, lines 43-48 of Briegs).

(E) Referring to claims 8 and 9, Colon does not disclose wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information

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before an instruction to obtain informed consent and wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

Briegs discloses wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before an instruction to obtain informed consent and wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent (col. 8, lines 1-39 of Briegs).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Briegs within Colon. The motivation for doing so would have been to record general information on the individual subjects and to confirm that the protocol is being conducted properly (col. 8, lines 10-36 of Briegs).

(F) Referring to claim 10, Colon discloses wherein said first plurality of workflow tasks include an instruction to enroll a patient into a clinical trial (col. 5, lines 25-35 of Colon).

(G) Referring to claim 11, Colon discloses wherein said first plurality of workflow tasks include an instruction to enroll a patient into a clinical trial (col. 5, lines 25-35 of Colon).

(H) Referring to claim 139, Colon discloses wherein said post-enrollment workflow tasks include patient management tasks (col. 6, lines 1-14 of Colon).

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5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Briegs et al. (US 7,054,823 B1), and further in view of Cimino ("Distributed cognition and knowledge-based controlled medical terminologies").

(A) Referring to claim 3, Colon and Briegs do not disclose wherein said database identifies a term by reference to a controlled medical terminology database.

Cimino teaches that controlled medical terminologies (CMTs) are at the heart of most medical systems (pages 154 & 162 of Cimino).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cimino within Colon and Briegs. The motivation for doing so would have been to enable data sharing and coordination of multiple applications (page 161 of Cimino).

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1, 4, 5, 8, and 9 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's additional arguments filed 12/6/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 12/6/06.

(1) Applicant argues at page 22 that Cimino does not appear even to mention clinical trials, much less suggest that CMTs can be used in a database that identifies widely disparate features of a clinical trial protocol. The Examiner's citation to Cimino p. 161

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as motivating such a combination is to no avail because there Cimino was speaking of patient care applications, not clinical trial protocols.

(A) In response to applicant's argument that Cimino does not appear even to mention clinical trials, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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In

2-14-07

  
JOSEPH THOMAS  
SUPERVISORY PATENT EXAMINER